中医药临床实效研究——中药注射剂注册登记式医院集中监测方案解读

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中文摘要:中药注射剂安全性问题一直是国家和百姓关注的焦点问题,开展大规模的中药注射剂临床安全性研究对于保证百姓安全用药有重要的影响,该文对于研究方案设计中的目的、试验类型的选择及特点、样本量的确定、结局指标的定义及伦理问题等内容进行重点解读。该研究为多中心、大样本、注册登记式的安全性监测研究,其目的是获得中药注射剂的不良反应发生率,根据"三例原则"确定每个中药注射剂品种样本量为3万例,所观察患者均为住院患者,研究的终点结局为发生严重不良反应。该研究结合条形码系统与医院信息系统确保纳入研究单位中的全部使用被观察中药注射剂品种的患者,注册登记表采用ABC 3种表格共同采集数据。

中文关键词:实效研究 中药注射剂 安全性再评价 注册登记研究 方案解读

Clinical outcomes research of traditional Chinese medicine——introduce registry intensive hospital monitoring study protocol of traditiona Chinese medicine injection's safety

Abstract: Traditional Chinese medicine(TCM) injection's safety problems has been paid attention for the country and people, TCM injection's labels described the adverse reactions always shows "unclear" or blank, especially the adverse drug reactions(ADR) rates hardly reported. To save the problem, large-scale safety surveillance of TCM injection research is very important. The article introduces the research aim, research type, simple size, outcomes and ethic problem during make the plan. It is a multi-center, large sample size, registry research program about TCM injections safety monitoring. The aim is to get the ADR's rate of TCM injections. According to the "three rules", each of the TCM injection will be observed for 30 000 cases which are inpatients. The research adopt to using the barcode system and hospital information system(HIS) & laboratory information management system(LIS) to make sure enroll all patients. Case report file (CRF)is used for record patient's information which contained 3 types(A,B,C) tables. Most of people just need to fill table A, and the patient need to fill table B when they have ADR. The outcome of the research is severe ADR. Abide by the international ethical principle to keep the patient's right.

keywords:outcomes research traditional Chinese medicine injections safety surveillance registry study research protocol

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